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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,225	05/04/2001	Kenichiro Shiroyama	Q64175	6389
65565 7590 07/25/2007 SUGHRUE-265550 2100 PENNSYLVANIA AVE. NW WASHINGTON, DC 20037-3213				
			EXAMINER CHANNAVAJJALA, LAKSHMI SARADA	
			ART UNIT 1615	PAPER NUMBER
			MAIL DATE 07/25/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/848,225	<b>Applicant(s)</b> SHIROYAMA ET AL.	
	<b>Examiner</b> Lakshmi S. Channavajjala	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 7 and 12-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7 and 12-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Receipt of RCE, amendment and response dated 4-30-07 and amendment and response dated 5-23-07 is acknowledged.

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4-30-07 has been entered.

Claims 7 and 12-20 are pending.

#### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 7 and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,294,444 in view of US 5,641,495 to Jokura et al (Jokura).

Nakamura teaches a transparent or semi-transparent cosmetic composition comprising an amphipathic lipid, nonionic surfactant, ionic surfactant and an aqueous medium (abstract, col. 2, lines 1-18). The amphipathic lipids of the Nakamura includes ceramides such as those described by formula I. Nakamura teaches the non-ionic

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surfactant of instant claim 13 (col. 3, lines 1-5 & tables 2 and 3), cholesterol and fatty acids (table 2). The amounts of ceramides, non-ionic surfactants, fatty acids and cholesterol in the composition taught by Nakamura are within the instant claimed ratios (table 2). With respect to the claimed method step of mixing lipid composition while heating at 80 -120 degrees C and heating water at 80 to 100 degrees C, Nakamura teaches that the components of table 3 were mixed and melted at a temperature of 85-90 degrees C (within the heating temperature of instant claims), followed by addition of hot water (Col. 4, lines 51-55). While Nakamura fails to state the specific temperature of water, absent evidence to the contrary, the term "hot water" includes boiling water, which is 100 degrees C or water as hot as 80 C. Nakamura also teaches that the compositions do not irritate the skin, as claimed (col. 1, lines 65-68).

Nakamura teaches ceramides, glycerocermides and ceramide derivatives, but does not teach the ceramides having the structural formula of instant claims.

Jokura teaches a skin cosmetic composition that is less irritating, comprising a ceramides, a dicarboxylic acid and a salt of dicarboxylic acid. Jokura teaches that the composition can include ceramides as well as pseudoceramides, represented by formula 1 and 2, respectively (col. 2, lines 7-30). In particular, formula 2 of Jokura meets the description of ceramides formula of Nakamura. Jokura also teaches linear or branched, saturated or unsaturated ceramides such as N-oleoylsphingosine or N-(12-hydroxyoctadecanoyl sphingosine or N-(16-hydroxyhexadecanoyl) sphingosine (col. 2, lines 40-65 and col. 3, lines 1-10), which meet the claim requirement of natural ceramides (claim 15).

Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to include ceramides (of Jokura) in the composition of Nakamura to prepare a skin cosmetic composition that is transparent as well as less irritating because Jokura recognizes ceramides as well as pseudoceramides as equivalent in their skin excellent moisturizing effect as well as their low skin irritation. Thus, a skilled artisan would have expected to achieve a transparent skin moisturizing composition that is less irritating to the skin.

Further, examiner presents the arguments from advisory action dated 12-16-05 as follows:

Applicants argue that the formula I of Jokura require a double bond adjacent to R2 position that is not required in the instant claims. However, instant claims require R1 (equivalent position of R2 of Jokura) be a hydrocarbon, which can include double bond containing hydrocarbon. Instant claims do not exclude the double bond containing hydrocarbons of Jokura. It is argued that while the reference teaches ceramides and pseudoceramides in excellent skin moisturization and low skin irritation, it is the combination of components (A), (B) and (C) which exhibits such effects and do not arise from the sole use of component (A) which is a ceramide of formula (1) or a pseudoceramide of formula (2). Instant claims do not exclude the combination of components taught by Jokura. It is argued that if Nakamura were to be combined with Jokura, the ceramide would be the ceramide of formula (1) of Jokura. However, as explained above, the ceramide of formula (1) of Jokura and the natural ceramide of

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claim 15 of the present application are not different compounds. Accordingly, the argument is not persuasive.

Claims 7 and 12-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,294,444 in view of US 6,355,232 to Kaneko et al (Kaneko).

The teachings of Nakamura have been described above. Nakamura fails to teach the claimed optically active compounds.

Kaneko teach skin protective compositions comprising erythro (2S, 3R) type of ceramides having the structural formula I –VI (col. 2, lines 15 through col. 3, lines 57). In particular, the ceramides of structural formula I meets the claimed structure II of claim 15. Kaneko also suggests a combination of amphipathic surfactants such as fatty acids, fatty alcohols etc., and cholesterol or a phytosterol, in the composition (col. 3, lines 58 through col. 4, lines 28). It would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to replace the ceramides of Nakamura, with the optically active ceramides of Kaneko because Kaneko teaches that the optically active ceramides exert remarkable water-barrier functions in skin protection compositions, as opposed to the racemates and significantly higher water holding capacity than racemates and pseudoceramides (col. 1, lines 59-67 and col. 8, lines 10-15). Thus, a skilled artisan would have expected that the ceramides of Kaneko to function better than the ceramides or pseudoceramides of Nakamura. While Kaneko

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fails to teach the specific ceramides of claims 18-20, in the absence of establishing an unexpected result with respect to the specific active ceramides taught by Kaneko, one of an ordinary skill in the art at the time of the instant invention was made would understand from the teachings of Kaneko that the 2S, 3R type of ceramides (optically active) are significantly more efficient in their skin moisturizing effect than the racemates and pseudoceramides because Kaneko teaches that the water restraining capacity of optically active ceramides is higher than the other ceramides (col. 8, lines 18-56).

With respect to Nakamura and Kaneko, it is argued that the ionic surfactant is not beneficial to the instant composition and instead may cause irritation. However, applicants agree that the instant language allows for the presence of the above surfactants. It is further argued that instant composition is in a clear state by a combination of four components and that the ionic surfactants and polyhydric alcohols of Nakamura are not essential. However, applicants agree that the products of Nakamura also include transparent products, which are the same as instant clear products. Therefore, the rejections have been maintained.

***Response to Arguments***

Applicant's arguments filed 5-23-07 have been fully considered but they are not persuasive.

Applicants offer the following remarks in the response dated (4-30-07):

In Nakamura, an ionic surfactant is a mandatory component. Therefore, when (A) amphiphatic lipid, (B) nonionic surfactant and (C) ionic surfactant are mixed and dissolved, polyhydric alcohols such as glycerin and optional alcohols such as ethanol are necessary. Specifically, polyhydric alcohols such as glycerin and optional alcohols such as ethanol are necessary in order to dissolve the (C) ionic surfactant. In the present invention, an ionic surfactant is not necessary; Accordingly, when components (A) to (C) and optional (E) sterol compound are uniformly mixed and dissolved, it is not necessary to formulate polyhydric alcohols therein. In this regard a polyhydric alcohol is not a mandatory component in the present invention (see Example 1). In the present invention, polyhydric alcohol is simply used in a secondary manner and is added when necessary. It is not a mandatory component. As a consequence, depending on whether an ionic surfactant is necessary or not, the preparation methods involved are different. Thus, the preparation method of the present invention is different from that in Nakamura. It is not believed that Jokura is relied upon for any method teaching.

Applicants' arguments are not persuasive because while it is argued that polyhydric alcohol is not essential, instant claims do recite the said components and in particular also recite specific amounts. Because instant claims also require the same component, the transitional phrase does not exclude polyhydric alcohol. With respect to the argument regarding a nonionic surfactant, applicants have not shown how the presence of the nonionic surfactant of Nakamura affects the basic and novel characteristics of the composition.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.00 AM -4.00 PM.

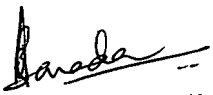


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AU 1615  
July 15, 2007

  
LAKSHMI S. CHANNAVAJJALA  
PRIMARY EXAMINER